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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-20762-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. There were no comments received during the first public review of this ICR. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS-OS-20762-30D for reference.

**Information Collection Request Title:** HHSAR 352.227-11 Patent Rights -- Exceptional Circumstances and 352.227-14 Rights in Data - Exceptional Circumstances

**Abstract:** HHS found that systematically, over a period of several years, when Determinations of Exceptional Circumstances (DECs) were executed, additional legal protection for the patent and data rights of third parties beyond those covered by FAR were necessary. A decision was made to add two clauses - 352.227-11 Patent Rights -- Exceptional Circumstances and 352.227-14 Rights in Data - Exceptional Circumstances - to the HHS supplement to the FAR, the HHS Acquisition Regulation (HHSAR), to provide the additional legal protection required. These clauses would ensure that providers of proprietary material(s) to the government will retain all their preexisting rights to their material(s), and rights to any inventions made under a contract or subcontract (at all tiers), when a DEC has been executed. Rights in data regulations concern the rights of the Government, and organizations with which the Government contracts, to information developed under such contracts. The delineation of such rights is necessary in order to protect the contractor's rights to not disclose proprietary data and to insure that non-proprietary data developed with public funds is available to the public. As these HHSAR clauses would be used in lieu of the related FAR clauses, the clauses also address the patent and data rights currently covered in FAR clauses 52.227-11 and 52.227-14 prescribed under FAR part 27. It is the policy and objective of the Government to : (1) Use the patent system to promote the use of inventions arising from federally supported research or development; (2) Encourage maximum participation of industry in federally supported research and development efforts; (3) Ensure that these inventions are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; (4) Promote the commercialization

and public availability of the inventions made in the United States by United States industry and labor; (5) Ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and (6) Minimize the costs of administering patent policies.

**Need and Proposed Use of the Information:** In order to accomplish the objectives described above through the clauses, it will be necessary to collect the information described below. All submissions are considered critical to the Government ensuring the patent and data rights of the Contractor, Government and third parties are protected appropriately.

**Likely Respondents:** It is anticipated that the respondents to the collection of information will be the prime contractor(s), subcontractor(s) and third party providers for contracts awarded that include the two clauses 352.227-11 Patent Rights -- Exceptional Circumstances and 352.227-14 Rights in Data - Exceptional Circumstances.

**Identify type of respondents:** It is anticipated that technical, legal, management and administrative personnel from the prime contractor(s), subcontractor(s) and providers of third party materials for contracts awarded that include the two clauses 352.227-11 Patent Rights -- Exceptional Circumstances and 352.227-14 Rights in Data - Exceptional Circumstances will provide the responses to the information collection required.

**Burden Statement:** Clause 352.227-11 contains the following information collections.

- a) A request for a determination of whether the Contractor or the employer inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer;
- b) The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Office and to the Director, Division of Extramural Inventions and Technology

Resources (DEITR);

- c) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: 1. Establish or confirm the rights the Government has throughout the world in Subject Inventions ... and 2. convey title to a Third party assignee ...and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention;
- d) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention made under contract;
- e) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all Subject Inventions or stating that there were none;
- f) The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency; and
- g) All invention disclosures and requests for greater rights shall be sent to the Agency Contracting officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to... <http://www.iEdison.gov>.

Clause 352.227-14 contains the following two collections of information.

- h) “Accordingly, the Contractor will provide the Contracting Officer a copy of any proposed publication or other public disclosure relating to the proposed publication or other public

disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure.” This information collection is being done to insure that the Contractor does not prematurely publish information concerning possible inventions made under this contract so that the ability to obtain patent protection on such inventions is adversely affected.

i) “The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings.” This information collection is being done to preserve the Government’s right to cancel or ignore the markings at any time after the stated period, making the data no longer subject to any disclosure prohibitions.

**Total Estimated Annualized Burden – Hours:**

Information Collection (see above list “Burden statement” for legend)	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden Hours
a)	63	1	8	504
b)	63	1	12	756
c)	63	3	12	2268
d)	63	3	14	2646
e)	63	1	10	630
f)	63	1	8	504
g)	63	3	8	1512
h)	63	3	3	567
i)	63	3	8	1512
TOTAL	63	19	83	10,899

Darius Taylor

Deputy, Information Collection Clearance Officer.

4150-24P

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